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10/748,706

12/30/2003

Mark Lester

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07/19/2006

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CHASE TOWER
111 MONUMENT CIRCLE
SUITE 3250
INDIANAPOLIS, IN 46204

EXAMINER

SNOW, BRUCE EDWARD

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 07/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/748,706 | Applicant(s) LESTER ET AL. | |
| | Examiner Bruce E. Snow | Art Unit 3738 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 May 2006.
 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) ☐ Claim(s) _____ is/are allowed.
 6) ☒ Claim(s) 1-19 is/are rejected.
 7) ☒ Claim(s) 20 is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments filed 5/11/06 have been fully considered but they are not persuasive. Applicant felt it necessary to amend originally filed independent method claim 1, only to add a new and broader independent claim 19. Applicant states:

"Claims 19 and 20 have been added. These claims recite novel and non-obvious limitations. Accordingly, claims 19-20 are believed to be allowable over the prior art. Specifically, claim 19 recites the step of "mating the bone tissue feature with the feature of the implant while the natural soft tissue is still attached to the resected portion of bone." As discussed above, Lee discloses the mating of a bolt within a slot. Lee does not disclose a bone tissue feature that mates with a feature of an implant. Therefore, claim 19 recites novel and non-obvious limitations with respect to Lee.

Referring to the rejection as being anticipated by Lee, the Examiner noted that the bore 53 was interpreted as the mating bone tissue feature which mates with "the feature of the implant" 20. Applicant fails to state why this interpretation is incorrect or unreasonable.

Regarding claim 13, applicant argues that the bolt is a component separate from the main prosthesis which is not commensurate with the scope of the claim which fails to define "main" body. The rejection clearly states that the body includes a surface, such as a surface of the bolt, which is configured to engage a complementary feature formed in the removed bone.

Regarding the rejection as being anticipated by Caldarise et al, applicant amended claim 13 to overcome the rejection under 112, second paragraph, and states that this overcomes the rejection under 102. This is not good enough. Applicant further

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argues that Caldarise recesses' are not located on the recessed bone portions. The Examiner notes that claim 13 is a device claim and not a method claim; it is the Examiner's position that the noted mechanical engagement features are fully capable of fulfilling the functional language.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 has been amended adding, *"the complementary feature of the implant does not extend completely through the removed portion of bone"* which is new matter. Referring to applicant's figure 6 and specification page 6 which teaches, *"mating feature 25 cut into the bone portion T can extend along the entire cut surface C as represented by the dashed lines in FIG 6"*. The Examiner interprets this as extending completely through the removed portion of bone.

Allowable Subject Matter

Claim 20 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000.

Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 13-14, 16, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al (3,939,498).

Lee teaches a method for repair of a joint comprising the steps of:
removing a portion of a bone 53 having natural soft tissue attached thereto;
implanting an implant 10 within the remaining bone leaving an exposed surface of the implant;

preparing a surface of the removed portion of bone to provide the surface with a surface feature (bore 54) to mechanically interlock with a complementary feature (member 20) defined on the exposed surface of the implant', and

mechanically engaging the surface feature of the removed portion of bone with the complementary feature of the implant when the implant is within the remaining bone while the natural soft tissue is still attached to the removed portion of bone.

Regarding claim 10, mechanical fastener, see fastener 40.

Regarding claims 13-18, as far as the scope can be determined, the following is made of record:

Claim 13: stem 13, body 10, mechanical engagement feature 14 or 20. Note that the slot can be used to accept a complementary feature formed in the trochanter. Said opening has "diverging opposing faces" which contain the enlarged end portion 22.

Claims 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Caldarise et al (6,008,431).

Caldarise et al teaches an implant comprising:

A stem 25 configured for implantation in a bone of a joint; and

a head configured to replace a portion of the articulating aspect of the bone, said body including a surface 28 defining a mechanical engagement feature configured to engage a complementary feature formed in a removed portion of the articulating aspect of the bone. Regarding the dovetail, see figure 2.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al (3,939,498) in view of Harwin (5,163,961) and/or Galline et al (4,889,110).

Lee et al teaches the implant as taught above, however, is silent regarding additional anchoring means of the trochanter. Harwin teaches an screw 9 and hole 10a and Galline et al teaches cerclage cable. It would have been obvious to one having ordinary skill in the art to have utilized either/both of the screw and cable as taught in

the art or bone cement which is well known in the art to provide additional anchoring of the implant as deemed necessary by the surgeon.

Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caldarise et al (6,008,431) in view of Harwin (5,163,961) and/or Galline et al (4,889,110).

Caldarise et al teaches the implant as taught above, however, is silent regarding additional anchoring means. Harwin teaches an screw 9 and hole 10a and Galline et al teaches cerclage cable. It would have been obvious to one having ordinary skill in the art to have utilized either/both of the screw and cable as taught in the art or bone cement which is well known in the art to provide additional anchoring of the implant as deemed necessary by the surgeon.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any


extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E. Snow whose telephone number is (571) 272-4759. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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BRUCE SNOW
PRIMARY EXAMINER